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| YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202 | | | EXAMINER MARCETICH, ADAM M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,757

Applicant(s)

WIGHTMAN, PAUL

Examiner

Adam Marcetich

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>28 February 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. Examiner notes a typographical error on the bibliographic data sheet. Under the heading "FOREIGN APPLICATIONS," the entry 0308442.9 will be changed to 0308552.9 for consistency.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 19-21, 23, 27-30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Birbara (US Patent 5,894,608).
5. Regarding claim 19, Birbara discloses a urine collection device for attachment to a pump and for a user in a supine, or reclined position, said device including:

an open-mouthed container having a rim around the mouth for being urged in use to seat generally around the periphery of the urine discharge region to receive urine discharged from the urethra (column 5, lines 62-66, column 6, lines 40-41 and 52-54; Figs. 1-2, receptacle (no element number) and Figs. 4-5, receptacle 12);

the container being adapted to fit between the legs of a user in a supine or reclined position (column 5, lines 20-26),

the container having at its lower part a reservoir basin in which fluid may collect in use when the container is applied to a user in a supine or reclined position (column 6, lines 52-54 and Figs. 4-5, lower part of manifold region 16 capable of collecting fluid when user is in a supine or reclined position); and

an outlet in the lower part of the reservoir basin through which urine may be drawn from the container (column 6, lines 54-57 and Figs. 4-5, outlet 17);

characterized in that the rim has a perineal wall portion adapted in use to engage edgewise with the perineum to effect a fluid tight seal (column 7, lines 6-7 and Figs. 4-5, upper rim of receptacle 12 capable of forming seal with user); and

and in that the container is provided with a vent above the liquid level in the reservoir basin in use (column 6, lines 52-57 and Figs. 4-5, orifices 15).

6. Regarding claim 20, Birbara discloses a urine collection device wherein said rim is generally of oblate curvilinear form, wherein a broader, upper end region of the rim is adapted to be seated against the mons pubis (pubic bone region), and a narrower lower end region of the rim is adapted to be seated against the perineum, in use (column 5, lines 20-26). It naturally follows that a user would position the device as needed during use.

7. Regarding claims 21 and 27, Birbara discloses a urine collection device wherein the inner surface region of the container extending inwardly from the lower end region of the rim defines a downwardly-inclined weir surface or one weir plate means extending

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between opposed portions of the rim and extending into the basin region of the container (column 6, lines 41-45 and Figs. 4-5, inner cone 13).

8. Regarding claim 23, Birbara discloses a urine collection device wherein the reservoir basin is defined at least partly by a back wall portion and a bottom wall portion which converge downwardly towards said outlet (Figs. 4-5, receptacle 12 having front and back walls converging towards outlet 17).

9. Regarding claim 28, Birbara discloses a urine collection device wherein the outlet includes an tubular portion integral with the container and having a drain inlet end which is located at the lowermost portion of the reservoir basin, and which extends upwardly to terminate in a drain outlet end (column 8, lines 65-66 and Fig. 10, lower portion of urine receptacles 65 connected to hose 64).

10. Regarding claim 29, Birbara discloses a urine collection device wherein the rim has an inturned resiliently deformable lip extending around a part thereof for seating against the user's body and providing an internal peripheral gutter (column 6, lines 46-51 and Figs. 4-5, receptacle 12 having inturned lip and forming internal peripheral gutter at region between inner cone 13 and manifold region 16).

11. Regarding claim 30, Birbara discloses a urine collection device wherein said vent includes a breather tube disposed generally vertically, the upper end of said tube being located to the exterior of said container, to prevent escape of urine (column 7, lines 9-21 and Figs. 4-5, lower orifice 19 substantially comprising a tube).

12. Regarding claim 32, Birbara discloses a urine collection device comprising:

a suction pump for applying suction to said device (column 9, lines 13-17 and Fig. 10, fan 73 and electric motor 74); and

a container for receiving urine drawn from said collection device by said suction pump (column 8, lines 60-64 and Fig. 10, urine collection container 63).

13. Regarding claim 34, Birbara discloses a urine collection device wherein said vent is sized such that, in use, when the urine collection device is applied to the user, and the suction pump operated, a slight negative pressure is present in the inside of the device to aid location and sealing of the device against the user (column 5, lines 27-48).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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16. Claims 22, 26 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birbara (US Patent 5,894,608).

17. Regarding claim 22, Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks a specific notional contact plane which in use lies at between about 100° to 135° to the horizontal when the user is reclined or supine. Since the combination of references provides for all structural elements as claimed, it will be within the skill of those skilled in the art to adjust the notional contact plane angle based on the desired degree of urine allowed to collect within a container. See in re Bosch and Slaney 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

18. Regarding claim 26, Birbara discloses the invention as substantially claimed, including a back wall portion. See above. However, Birbara lacks a back wall portion lying at an angle of between about 120° and 160° as claimed [claim 8]. Since the combination of references provides for all structural elements as claimed, it will be within the skill of those skilled in the art to adjust the back wall portion angle based on the desired degree of urine allowed to collect within a container. See in re Bosch and Slaney 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

19. Regarding claim 35, Birbara discloses a urine collection device for attachment to a pump and for a user in a supine, or reclined position, said device including:

an open-mouthed container having a rim around the mouth for being urged in use to seat generally around the periphery of the urine discharge region to receive urine discharged from the urethra (column 5, lines 62-66, column 6, lines 40-41 and 52-54; Figs. 1-2, receptacle (no element number) and Figs. 4-5, receptacle 12);

the container being adapted to fit between the legs of a user in a supine or reclined position (column 5, lines 20-26);

the container having at its lower part a reservoir basin in which fluid may collect in use when the container is applied to a user in a supine or reclined position (column 6, lines 52-54 and Figs. 4-5, lower part of manifold region 16 capable of collecting fluid when user is in a supine or reclined position); and

an outlet in the lower part of the reservoir basin through which urine may be drawn from the container (column 6, lines 54-57 and Figs. 4-5, outlet 17).

Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks a back wall portion lying at an angle of between about 120° and 160° as claimed [claim 35]. Regarding rationale and motivation, see discussion of claims 22 and 26 above.

20. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birbara (US Patent 5,894,608) in view of Metz et al. (US Patent 4,889,532).

21. Regarding claim 31, Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks guard surfaces as claimed [claim 31]. Metz discloses a container provided with guard surfaces, capable of preventing inadvertent blocking of the upper end of said tube by the hand of the user in use (column 5, lines 10-18, 33-37 and 51-53; Fig. 2, apertured cap 32 having rib 35). Metz provides the advantage of preventing an object from blocking the vent with rib 35. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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the invention of Birbara as discussed with the guard as taught by Metz in order to prevent an object from blocking a vent.

22. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birbara (US Patent 5,894,608) in view of Kimura et al. (US Patent 4,360,933).

23. Regarding claim 33, Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks a urine sensor as claimed [claim 33]. Kimura discloses a urine collection device has associated therewith a urine sensor and said system is operable on detection of urine by said sensor to start a suction pump (column 3, lines 26-54, especially lines 31-36 and 52; Fig. 1(a), electrodes e and e', urine receiver 2 and vacuum suction device v). Kimura provides the advantage of ensuring that suction is activated when needed by a user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Birbara as discussed with the urine sensor as taught by Kimura in order to ensure that suction is activated when needed by a user.

24. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birbara (US Patent 5,894,608) in view of Vergano (US Patent 5,885,204).

25. Regarding claim 25, Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks said back wall portion and said bottom wall portion

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converge at an angle of between 90° and 120° as claimed [claim 25]. Vergano discloses a back wall portion and a bottom wall portion converging at an angle of between 90° and 120° (column 4, lines 1-7 and Fig. 4, flange 14 disposed at angle theta, between 20-135°). Therefore Vergano makes obvious the claimed range of between 90° and 120° with a range of between 40° - 270°. Vergano provides the advantage of fitting a urine collection device to a user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Birbara as discussed with the angle as taught by Vergano in order to fit a urine collection device to a user.

26. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birbara (US Patent 5,894,608) in view of Snyder (US Patent 6,592,560).

27. Regarding claim 24, Birbara discloses the invention as substantially claimed. See above. However, Birbara lacks a urine collection device wherein the reservoir basin has a capacity of at least 10ml and preferably at least 20ml as claimed [claim 24]. Snyder discloses a urine collection device wherein the reservoir basin has a capacity of at least 10ml and preferably at least 20ml when the device is applied to a user in a supine position (column 6, lines 5-10 and Figs. 3-4, device 100 capable of holding up to 400ml of urine). Therefore Snyder overlaps the claimed volume of at least 10-20 ml. Snyder

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provides the advantage of holding a sufficient volume of urine as released by a user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Birbara as discussed with the urine capacity as taught by Snyder in order to hold a sufficient volume of urine.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

❖ Martin (US Patent 4,631,061)

❖ Young (US Patent 6,299,606)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761

Adam Marcetich

AMM

TATYANA ZALUKA
SUPERVISORY PRIMARY EXAMINER

Tatyana Zaluka